

Atty. Dkt. No. EPI3007B
(formerly TSRI 184.2C2)

Goodman never seriously considered that his discovery could be extended to heteromultimeric proteins. Furthermore, the Patent Office rejected originally filed claim 1 and other claims of the Goodman application as being nonenabled.

Claims 1-5, 7, 8, 10 and 11 are rejected under 35 U.S.C. 112, first paragraph, as the disclosure is enabling only for claims limited to Agrobacterium-mediated dicot transformation with chimeric genes comprising opine synthase promoters and structural genes encoding human interferon or antibiotic resistance as per pages 10-18. . . . Given the unpredictability inherent in the art, undue experimentation would be required by one of ordinary skill in the art to determine DNA sequences for non-disclosed mammalian peptides or promoters and to develop transformation vectors resulting in detectable expression of stable, bioactive peptides as claimed in claims 1-5, 8, 10 and 11.

U.S. serial No. 760,236, Office Action 6/9/87, pages 3-4 (Office Action attached as EXHIBIT 2). Goodman failed repeatedly to convince the examiner to withdraw the rejection over enablement and eventually appealed the case to the Board of Patent Appeals and Interferences. On September 29, 1989, the Board affirmed the rejection for non-enablement. The Board's decision makes clear that the patent is not enabling for any mammalian peptide other than interferon.

It appears to have been accepted by the examiner that the experimental portion of appellants' specification enables one of ordinary skill in the relevant art to repeat that which appellants have done, i.e., obtain the expression of an interferon gene through the use of a transformed Ti-plasmid in dicotyledonous plant cells. In view of the very same high order unpredictability of success in extrapolating reported procedures to different systems, e.g., different genes, different vectors, and different hosts, discussed above, appellants' arguments that their disclosure enables one of ordinary skill to practice the inventions claimed more generally in the broader claims without the exercise of undue experimentation are unreasonable on their face.

BPAI Decision, page 4-5 (BPAI decision attached as EXHIBIT 3).

Thus, there is no basis to support that view that Goodman taught to separately express the heavy or light chains of an immunoglobulin. Goodman refers to